

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

EXERGEN CORPORATION,)	
)	
Plaintiff,)	CIVIL ACTION NO.
)	12-12243-DPW
v.)	
)	
BROOKLANDS INC.,)	
)	
Defendant.)	

MEMORANDUM AND ORDER
August 28, 2015

In this action, Exergen Corporation alleges that Brooklands, Inc. has infringed United States Patent No. 7,787,938 (" '938 patent") by selling infrared thermometers. Brooklands moves for summary judgment on the affirmative defenses that the '938 patent is invalid under 35 U.S.C. § 101 (unpatentable subject matter), § 102 (anticipation), and § 103 (obviousness). Brooklands also moves for Rule 11 sanctions against Exergen and its counsel, Sunstein Kann Murphy & Timbers LLP ("Sunstein").

I. BACKGROUND

Exergen asserts that Brooklands has infringed two method claims of the '938 patent, which is entitled "Temporal Artery Temperature Detector." These are claims 51 and 54.

Claim 51 of the '938 patent claims: "A method of detecting human body temperature comprising: measuring temperature of a

region of skin of the forehead; and processing the measured temperature to provide a body temperature approximation based on heat flow from an internal body temperature to ambient temperature."

Claim 54 of the '938 patent claims: "A method of detecting human body temperature comprising: measuring radiation as target skin surface of the forehead is viewed, and processing the measured radiation to provide a body temperature approximation based on heat flow from an internal body temperature to ambient temperature."

Exergen's CEO, Dr. Francesco Pompei, is the named inventor of the '938 patent as well as of numerous other patents held by Exergen related to thermometry. The '938 patent, which issued on January 25, 2008, is a continuation of an application previously filed on September 11, 1998, and it references twenty-five of Dr. Pompei's own patents. Two of these patents are Patent No. 5,012,813 ('813), issued May 7, 1991, and Patent No. 5,653,238 ('238), issued August 5, 1997, which include claims directed to a radiation-detecting machine designed primarily to take measurements at the ear's tympanic membrane and convert it to internal body temperature. As discussed below, however, those two patents also included broader claims about measuring a target of biological surface tissue.

Exergen previously brought suit against manufacturers of forehead thermometers in *Exergen Corp. v. Wal-Mart Stores, Inc.*, No. 01-cv-11306-RCL (D. Mass.), consolidated with *Exergen Corp. v. CVS Corp.*, No. 02-cv-10436-RCL (D. Mass.), which included allegations that the defendants were manufacturing forehead thermometers that infringed certain Exergen patents – including the '813 and '238 patents, as well as Patent No. 6,319,206 ("'206 patent") – claiming a method and various devices for measuring temperature at the forehead. See *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009)(reversing jury finding of infringement of '813 patent). Exergen brought a similar claim in *Exergen Corp v. Kidz-Med, Inc.*, No. 1:08-cv-11416-DPW (D. Mass.) During the prior litigation, Exergen and Dr. Pompei made a number of statements about the language of these prior patents, which will be discussed below.

In this case, Brooklands filed a motion before claim construction for summary judgment of invalidity due to unpatentable subject matter under 35 U.S.C. § 101. This case thereafter was consolidated with two other pending matters for claim construction before Judge Stearns, who issued a claim construction decision on August 15, 2014. *Exergen v. Brooklands, Inc.*, 2014 WL 4049879 (D. Mass. August 15, 2014).¹

¹ *Exergen v. Kaz USA, Inc.*, No. 1:13-cv-10628, remains pending before Judge Stearns. Judge Stearns recently issued a

The claim construction provided by Judge Stearns largely tracks the plain language of the claims themselves. The parties agreed that the term "human body temperature" should be constructed as "the core temperature of a human being," and Judge Stearns construed "body temperature approximation" to mean "a temperature approximating human body temperature encompassing all such possible temperatures." *Id.* at *9.

After the claim construction, Brooklands filed additional motions for summary judgment on the issues of patent validity under 35 U.S.C. §§ 102 and 103. Partial discovery, specifically document production, had already occurred prior to the filing of these motions. Brooklands moved, however, for a stay of further discovery, which I have granted, pending resolution of these motions.

II. ANALYSIS

A. *Standard of Review*

Summary judgment is proper only when the movant shows that there is "no genuine dispute as to any material fact and the

Memorandum and Order denying Kaz's motion for summary judgment of invalidity because of obviousness, and allowing Kaz's motion for summary judgment of no willful infringement. *See Exergen Corp. v. Kaz USA, Inc.*, 2015 WL 4974167 (D. Mass. Aug. 20, 2015). The other consolidated case, *Exergen v. Thermomedics, Inc.*, No. 1:13-cv-11243, remains pending before Judge Casper. As of this date, motions for summary judgment on the bases of invalidity under 25 U.S.C. §§ 101, 102, and 103 are under consideration before her.

movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56. All reasonable inferences must be drawn in favor of the nonmovant, *Exergen*.

All patents are entitled to a presumption of validity. 35 U.S.C. § 282; see also *Minnesota Min. & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1301 (Fed. Cir. 2002) ("An issued patent is presumed valid and the burden is on the party challenging the validity of a patent to show that it is invalid by clear and convincing evidence.") Whether an inquiry into patentable subject matter under § 101 is subject to the same presumption of validity has recently become a matter of debate. Historically, § 101 analysis for patentable subject matter has been assessed with a presumption of validity. See *CLS Bank Intern. v. Alice Corp. Pty. Ltd.*, 717 F.3d 1269, 1284 (Fed. Cir. 2013), *aff'd* 134 S.Ct. 2347 (2014) ("as with obviousness and enablement, that presumption applies when § 101 is raised as a basis for invalidity in district court proceedings.").

In a concurring opinion in *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709 (Fed. Cir. 2014)(Mayer, J. concurring), Judge Mayer noted that because recent Supreme Court decisions make clear that the Patent and Trademark Office has "for many years applied an insufficiently rigorous subject matter eligibility standard, no presumption of eligibility should attach when assessing whether claims meet the demands of section 101." *Id.* at 720.

He further observed that the Supreme Court has not mentioned or applied any presumption of eligibility in § 101 cases in recent years. *Id.* at 720-21. In *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S.Ct. 2238, 2242-43 (2011), the Supreme Court discussed the requirement that patent invalidity be shown by clear and convincing evidence due to the presumption of validity. In its discussion, the court did not distinguish § 101 from §§ 102 and 103, which are plainly covered by the presumption. *Id.* Justice Breyer suggested in his concurring opinion that the "clear and convincing" standard arising from the presumption of validity applies only when a court is considering questions of fact, not questions of law. *Id.* at 2253. Whether the claims at issue here contain patentable subject matter is a question of law, see *In re Roslin Institute*, 750 F.3d 1333, 1335 (Fed. Cir. 2014), albeit one that may build on factual determinations. Given the plain language of 35 U.S.C. § 282 which codifies a general presumption of validity and the fact that no Supreme Court or Federal Circuit majority has disavowed the presumption of validity for § 101, I will apply the heightened standard to all three validity sections, although I agree with Justice Breyer that the presumption has less significance in the context of a largely legal determination.

In evaluating this motion for summary judgment, I must view the record "through the prism of the evidentiary standard of proof that would pertain at a trial on the merits . . . Thus, a moving party seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise." *Eli Lilly Co. v. Barr Labs., Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001)(citations omitted).

B. Unpatentable Subject Matter under Section 101

The statute outlining patentable subject matter, 35 U.S.C. § 101, contains broad language. It provides: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." The Supreme Court has held that based on the use of the term "any" in the statute, "Congress plainly contemplated that the patent laws would be given wide scope." *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010)(quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980)). The term "process" is defined by the Patent Act to mean "process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." 35 U.S.C. § 100(b). Claims 51 and 54 in the '938 patent are method claims.

Courts have long held that § 101 "contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S.Ct. 2347, 2354 (2014). An experienced Federal Circuit panel member thereafter criticized the Federal Circuit's own prior interpretation of § 101 as a "coarse filter" not designed to limit significantly what is eligible for a patent, and suggested instead that courts have a significant and active role to play at the § 101 analysis stage. *Ultramercial*, 2014 WL 5904902 at *10 (Mayer J., concurring). Such a realignment of approach has been prompted by a number of Supreme Court decisions in recent years requiring courts to conduct a more probing and demanding § 101 subject matter eligibility analysis than before. *See, e.g., Alice Corp.*, 134 S.Ct. at 2354-55; *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S.Ct. 2107, 2116 (2013); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289, 1293-94 (2012). Nevertheless, at the same time the concept of rigorous § 101 analysis has been expanding, the Supreme Court has reaffirmed that exceptions to patentability cannot be read too broadly because "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Mayo*, 132 S. Ct. at 1293.

The Supreme Court reaffirmed in *Alice Corp.*, 134 S.Ct. at 2355, that the two-part framework for § 101, drawn from its earlier decision in *Mayo*, 132 S. Ct. at 1296-97, controls the analysis of whether the subject matter of a particular claim is eligible to be patented.² Under this framework, a court must first "determine whether the claims at issue are directed to one of those patent-ineligible concepts" and, if so, whether the claims include "an element or combination of elements that are 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.'" *Alice*, 132 S.Ct. at 2355 (quoting *Mayo*, 132 S. Ct. at 1294).

The first part of the inquiry is easily resolved and essentially undisputed here. The claims in the '938 patent clearly are directed to a law of nature. The language of the

² The Federal Circuit's "machine or transformation test" is one tool for evaluating, but is not the definitive test for, patent eligibility. This test certainly does not trump the law of nature exclusion. *Mayo*, 132 S.Ct. at 1303. Particularly following *Alice*, which held that performing a conventional task on a computer is not patentable, courts have relied even less on this tool. I therefore note briefly, though without giving it much weight, that Exergen's '938 patent fails the machine-or-transformation test. Exergen claims that the surface temperature is "transformed" into an internal body temperature. Simply running an input through a mathematical equation or other law of nature, however, does not "transform" that input into the output.

"processing" step of claims 51 and 54 states that they process "the measured temperature [/radiation] to provide a body temperature approximation based on heat flow from an internal body temperature to ambient temperature." The claim construction did not change this language. Exergen acknowledges, as it must based on the language of the claim, that the "process" step of the claims involves the application of mathematical formulas that model heat transfer principles. Mathematical formulas are quintessential laws of nature that, standing alone, may not be patented. *Mayo* 132 S. Ct. at 1303 ("the cases have endorsed a bright-line prohibition against patenting laws of nature, mathematical formulas and the like . . ."). As the Supreme Court held in *Mayo*, "if a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features" that make it patentable under the second part of the framework. 132 S. Ct. at 1297.

Under the second part of the framework laid out in *Mayo*, I must ask whether "the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws". *Mayo*, 132 S. Ct. at 1297. I must consider whether the claims include "additional elements," other than the patent-ineligible concept, *Alice* 132 S.Ct. at 2355, that are

sufficient to transform the claim into patent-eligible subject matter. *Id.* at 2357. This second step requires an "inventive concept." *Id.*

At this step, I must look to the elements of the claims both individually and in combination within the claim. When examining the individual elements, I consider whether they are "well-understood, routine, [or] conventional," because such activity is "normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law." *Mayo* 132 S.Ct. at 1298. When considering the claim as a whole, I must consider the steps as an ordered combination to determine whether the claims add something to the law of nature that is not present when the steps are considered separately. While looking at the claim in its entirety, I may not disregard an element of a claim as simply being conventional or well-understood because "a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made." *Diamond v. Diehr*, 450 U.S. 175, 188 (1981).

The two steps in these claims are the "measuring" step, which involves measuring temperature or radiation at the skin of the forehead, and the "processing" step, which involves taking the data from the "measuring" step and a mathematical formula

that uses heat transfer principles to result in an output, an approximate core body temperature. Exergen directs its argument to the claim as a whole, not arguing that the step of measuring the temperature or radiation of forehead skin is sufficiently novel and unconventional on its own but rather that the notion that body temperature can be determined from surface skin temperature measured at the exposed site of the forehead is what transforms the claim into patent-eligible subject matter. In support of this argument, Exergen points to a statement by the American Society for Testing and Materials that "skin temperature can not [sic] be independently correlated with the internal body temperature" as evidence of the state of the art at the time that Dr. Pompeii made his discoveries and of the novelty of using an exposed skin surface to calculate internal body temperature.³

The Supreme Court has decided a number of cases concerning the patentability of a claim involving a natural law in the form of a mathematical formula. Exergen contends that its claim is similar to that in *Diamond v. Diehr*, 450 U.S. at 177-79. The

³ Brooklands challenges the American Society for Testing and Materials statement as hearsay, but it is not being proffered for the truth of the matter asserted – indeed, Exergen argues that it is an inaccurate statement. It is offered only as evidence of the state of the art to show that this was not a "well-understood, routine, conventional activity previously engaged in by scientists who work in the field." *Mayo*, 132 S. Ct. at 1298.

claim in *Diehr* involved a method for determining when a rubber-curing process was complete. The claimed steps included continuously monitoring the temperature of rubber in a mold, feeding the numbers to a computer, which used a mathematical equation to recalculate the curing time, and sending a signal from the computer to open the molds at the proper time. *Id.* The *Diehr* court found the process to be patent eligible although the equation itself was not, because the additional steps integrated the equation into the process as a whole. *Id.* at 187. The process itself was patent-eligible, and the court held that it did not become unpatentable simply because it involved an algorithm. *Id.*

By contrast, in *Parker v. Flook*, 437 U.S. 584 (1978), the Supreme Court found the claim not to be patent eligible. The claim in *Flook* concerned an improved method of adjusting alarm limits to signal danger or inefficiency in the catalytic conversion of hydrocarbons. The claim involved measuring the current level of a variable, such as the temperature, then using a mathematical algorithm to calculate the alarm limits and adjusting the system to reflect new alarm limit values. The Supreme Court assumed that the mathematical equation used in the process was novel but held that the additional steps other than the mathematical equation were not patentable because they were conventional and contained no "inventive concept." *Id.* at 594.

Thereafter, in the 2012 case of *Mayo*, the Supreme Court considered a claim for a process that helped calibrate the amount of a drug provided to a particular patient by providing the drug to the patient, measuring the amount of a compound from that drug in the patient's blood, and increasing or decreasing the dosage going forward based on whether it appeared in the blood in an amount greater or less than a concentration specified in the claim. 132 S.Ct. at 1295. *Mayo* held that the correlation between the concentration of this compound in the blood and the likelihood that dosage would need to be increased or decreased was a law of nature. *Id.* at 1296. The Court concluded that the additional step, primarily that of measuring the level of the compound in the blood, was a step that was necessary to apply the law of nature and found that the other steps were merely well-understood, routine, conventional activity, previously engaged in by those in the field. *Id.* at 1299.

The claims before me are closer to those in *Mayo* and in *Flook* than those in *Diehr*. The law of nature in the "process" step is the conversion of the skin temperature of the forehead into the internal body temperature. This step takes into account heat transfer principles, as well as variables specifically chosen to capture heat transfer, perfusion rate, and blood-specific heat at the forehead artery. '938 Patent,

3:32-35. Unlike in *Diehr*, the formula is not used to affect a physical transformation. It is also part of a much more simple and straightforward process. The only additional step added to this law of nature is taking a measurement of temperature or radiation at the forehead. The question is whether this one additional step is sufficient to establish patent eligibility.

In order to convert the skin surface temperature of the forehead into the internal body temperature, one must first collect the data to input into this formula. As the Federal Circuit held in *In re Grams*, "Given that the method of solving a mathematical equation may not be the subject of patent protection, it follows that the addition of the old and necessary antecedent steps of establishing values for the variables in the equation cannot convert the unpatentable method to patentable subject matter." 888 F.2d 835, 839 (Fed. Cir. 1989). See also *In re Richman*, 563 F.2d 1026, 1030 (C.C.P.A. 1977) ("notwithstanding that the antecedent steps are novel and unobvious, they merely determine values for the variables used in the mathematical formulae used in making the calculations. [They] do not suffice to render the claimed methods, considered as a whole, statutory subject matter."). Aside from the processing step, which is the mathematical formula used to convert the forehead surface skin temperature or radiation into internal body temperature, the sole additional step in this

claim involves collecting the data through measurement, a necessary step for determining the proper input for the mathematical formula.

Exergen insists that Dr. Pompei's invention of forehead thermometry in general so defied conventional wisdom that it cannot be considered to be routine or conventional. In *Ameritox, Ltd. v. Millenium Health, LLC.*, 2015 WL 728501, at *19 (W.D. Wis. Feb. 19, 2015), Judge Conley considered a urine drug screening protocol that was based on the idea of comparing a person's metabolite/creatinine ratio to the same ratio in a known population. Judge Conley held that whereas the Supreme Court in *Mayo* held that steps were conventional because they were "already engaged in by the scientific community," 132 S.Ct. at 1298, the inverse is also true: "if inventors engage in activities that run *counter* to scientific thought, those activities can hardly be considered conventional under § 101" and that "[w]hen invention is based on the combination of elements that cuts against the grain of scientific thought, this heightens the novelty of invention itself." *Id.* He concluded that the patent as a whole was addressed to patent-eligible subject matter because of processing steps that were found to be unconventional in part because the state of the art at the time of the invention suggested that such a screening could not be done. *Id.* at 27 ("Because the inventors cut against scientific

thought at the time of the invention, and because the invention targeted a specific problem in the field of urine testing, the court finds that there is sufficient inventive concept in the [patent] for the purposes of meeting the threshold test of section 101."). Similarly, Exergen claims that Dr. Pompei's invention of forehead thermometry solved a problem in health care through a method that, at the time, defied the conventional wisdom as to whether the forehead could be a suitable site for determining internal body temperature.

Without addressing whether I believe that *Ameritox* was correctly decided, I note that the process steps held unconventional in *Ameritox* were significantly more specific than those at issue here. The additional steps in *Ameritox* involved identifying and applying techniques that scientists were not using in the field at the time to solve the problem addressed by the patent – in fact, the existing art taught against being able to use the techniques applied to the urine sample in *Ameritox*. In contrast, here, the only step in the patent aside from the law of nature: identified in the formula for converting the surface forehead temperature into internal temperature is the step of measuring the forehead temperature or detecting radiation – a step that can hardly be considered unconventional in the field of thermometry, particularly once the conversion for forehead temperature was identified.

The patent in this case is more similar to that in *Celsis in Vitro, Inc. v. CellzDirect, Inc.*, 2015 WL 1523818 (N.D. Ill. Mar. 13, 2015), in which Judge Shadur held that a patent protecting processes for freezing liver cells was not directed to patent-eligible subject matter. In *Celsis*, the patent identified a law of nature: that certain liver cells were capable of being frozen and thawed more than once, although the prevailing thought was that they could only be frozen once. *Id.* at *7. Aside from the discovery that double freezing was feasible, the steps used to freeze and unfreeze the cells twice were the same as those that would be used to freeze and unfreeze the cells once, a practice that was already in wide usage. *Id.* Judge Shadur addressed the decision in *Ameritox*, noting both that he was not bound by its reasoning and also distinguishing that case from the one before him by noting that in *Celsis*, as in the case before me, "the combination of steps in the [patent] directly follows from the discovery of a law of nature." *Id.* at *7, n.7.

The Federal Circuit recently addressed similar facts in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015). In *Ariosa*, the patent claimed methods for detecting fetal DNA circulating in the blood of a pregnant woman. The Federal Circuit did not doubt that before the patent at issue, "no one was using the plasma or serum of pregnant mothers to

amplify and detect" fetal DNA, or that the method "reflects a significant human contribution." *Id.* at 1379. The discovery of a law of nature, such as the method for non-invasive fetal testing in *Ariosa* or the discovery of the BRCA1 and BRCA2 genes in *Myriad*, no matter how novel, cannot on their own amount to patentable subject matter, *id.* at 1379; see also *Myriad Genetics*, 133 S.Ct. at 2117. "Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." *Id.*

Exergen may well be correct that Dr. Pompei's discovery that surface skin measurements taken at the forehead reliably can be converted to accurate body temperature is novel and valuable. However, the additional step of measuring the surface skin of the forehead is a necessary, conventional step involving collecting the data needed to be plugged into the mathematical equations in the processing step. Measuring temperature or radiation is simply not an inventive or unconventional step in the field of thermometry. As the Supreme Court held in *Mayo*, 132 S.Ct. at 1294, "to transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words 'apply it.'" The process step of measuring temperature or radiation at the forehead does nothing more than direct a party to apply a law of nature, the heat flow conversion calculation

for the forehead. The claim lacks an inventive concept outside of the laws of nature and therefore is not eligible for a patent.

While my conclusion that the subject matter of the two method claims of the '938 patent at issue in this litigation are unpatentable under § 101 is sufficient to ground my grant of the motion for summary judgment, in the interests of completeness and because they are the predicates for the defendant's Rule 11 initiative, I turn to the alternative grounds – anticipation and obviousness – also urged by grounds for summary judgment.

C. Anticipation under Section 102

Brooklands argues that the '938 patent is invalid because it was anticipated by Exergen's own prior patents '813 and '238. Under 35 U.S.C. § 102, a person is not entitled to a patent if "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." A claim is considered anticipated "if each and every limitation is found either expressly or inherently in a single prior art reference." *King Pharm., Inc. v. Elan Pharm., Inc.*, 616 F.3d 1267, 1274 (Fed. Cir. 2010). Inherent anticipation occurs when a missing characteristic is not disclosed but is necessarily present in a prior reference. *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed.

Cir. 2003). With respect to § 102, a patent is presumed valid under 25 U.S.C. § 282. This presumption, however, can be rebutted by clear and convincing evidence, a standard that reflects the presumption of validity. *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 958 (Fed. Cir. 2014).

The '813 patent, filed in 1991, and the '238 patent, filed in 1997, each concern improved radiation detectors and components of radiation detectors. Both are primarily directed to conducting measurements at the tympanic membrane in the ear, but both also contain broader references to tissue beyond the tympanic membrane itself. The '813 patent references, for example, that the heat balance approach may be used "in other applications," 11:15-16, and refers to a radiation detector that "view[s] a target of biological surface tissue," Claim 7, 14:50-52 and also "a radiation detector as claimed in claim 7 wherein the biological surface tissue is tympanic membrane," Claim 8, 14:64-66. Similarly, the '238 patent is primarily directed to a device for detecting readings from the ear, but claims 34 and 36 of the patent each reference a sensor viewing "a target," whereas claim 37 specifies a detector adapted to sense radiation from an ear. 24:1-22. The '831 and '238 patents primarily disclose devices, whereas the '938 patent discloses methods. This distinction between machine and method, however, is not material because "a method claim will be anticipated by an

earlier device performing all of the operative steps of the method." *Schumer v. Laboratory Computer Systems, Inc.*, 308 F.3d 1304, 1309 n.3 (Fed. Cir. 2002).

Exergen argues that the '813 and '238 patents do not disclose "measuring temperature of a region of skin of the forehead" or "measuring radiation as target skin surface of the forehead is viewed" and that this "undisputed fact" – as evidenced by the lack of the word "forehead" in the prior art patents – "destroys Brooklands' anticipation argument."⁴ While Exergen is correct that the word "forehead" is missing from the express language of the patents, this does not resolve whether the broader references in the early patents, such as to "biological surface tissue" or a "target" other than the tympanic membrane or ear, are properly read to disclose the concept of measuring skin at the forehead. The question, then, is whether there is clear and convincing evidence that the broad terms of the early patents disclose the use of forehead skin as a source of measurement such that the devices of the earlier

⁴ Exergen does not explicitly concede that each of the other elements of the claims at issue in the '938 patent are anticipated, but does not challenge Brooklands assertion that they are. The '938 patent itself states that using the arterial heat balance is disclosed in the '813 patent and that the prior thermometers use the same function to determine internal core temperature using skin and ambient temperatures. '938, 1:48-52 and 3:15-23.

patents can be considered to perform the methods described in the '938 patent.⁵

Determining internal temperature from the forehead is plainly a narrower focus than determining internal temperature from "biological surface tissue" or a "target." The Federal Circuit has held that whether a generic disclosure necessarily anticipates everything within the genus is a factual determination that depends on "the specific disclosure and the particular products at issue." *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1083 (Fed. Cir. 2008).

In *Atofina v. Great Lakes Chemical Corp.*, 441 F.3d 991 (Fed. Cir. 2006), the Federal Circuit reversed a district court's ruling after a bench trial that certain claims had been anticipated. The Federal Circuit held that "the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus." *Id.* at 999. A prior patent disclosed a temperature range of 100-500 degrees Celsius

⁵ This same question undergirds what Brooklands presents as its inherent anticipation argument, which focuses on the contention that because forehead skin is a surface tissue, the earlier patents "necessarily" include forehead skin measurement. Inherent anticipation is invoked when a prior claim is silent about a characteristic that is necessarily part of the claim. *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). In contrast, Brooklands' argument relies on the language of the prior patents themselves, and is more accurately considered a regular, not inherent, anticipation claim.

as necessary for a claimed method for synthesizing a compound, and the patent at issue involved a process for synthesizing the same compound but with a narrow subset of the temperature range, 330-450 degrees Celsius. *Id.* The court held that the claimed range was significantly different from the range in the prior art, such that no reasonable fact finder could conclude that the prior art described the claimed range with sufficient specificity to anticipate the subsequent patent. *Id.*

By contrast, in *ClearValue, Inc. v. Pearl River Polymers, Inc.*, 668 F.3d 1340 (Fed. Cir. 2012), the Federal Circuit reversed a district court's denial of judgment as a matter of law after a jury verdict in favor of the patent-holder, finding that a patent was invalid as anticipated where the prior art patent concerned clarifying water of raw alkalinity less than 150 parts per million and the patent at issue in the suit concerned water with alkalinity less than 50 parts per million. *Id.* at 1345. The Federal Circuit contrasted *Atofina*, noting that the patent-holder had not argued that the lower alkalinity limit was "critical" or that the claimed method somehow worked differently at different points within the prior art's larger range. The court also noted that the patent-holder did not argue that the prior patent "fails to teach one of ordinary skill in the art how to use the claimed invention." *Id.* The Federal Circuit held that "unlike *Atofina* where there was a

broad genus and evidence that different portions of the broad range would work differently, here, there is no allegation of criticality or any evidence demonstrating any difference across the range." *Id.*

I cannot resolve this issue as a matter of law unless all reasonable fact finders would find that there is clear and convincing evidence that variation within a genus would make no difference for the claims at issue here and that a person of ordinary skill would have recognized measuring forehead temperature as a specific application of the broader categories in the prior patents. *OSRAM Sylvania, Inc. v. American Induction Technologies, Inc.*, 701 F.3d 698, 706 (Fed. Cir. 2012). "How one of ordinary skill in the art would understand the scope of the disclosure or, stated differently, how one of ordinary skill in the art would understand the relative size of a genus or species in a particular technology is of critical importance." *Id.* If there is not clear and convincing evidence as a matter of law, then this case could proceed to further fact finding on the § 102 anticipation defense.

Brooklands states that disclosure of external tissue surface is a "definite and limited set of locations that can be used to take measurements," and that "[u]pon reading the '813 and '238 patents, one of ordinary skill in the art, indeed, a layperson, would immediately envision that forehead skin is a

skin or external tissue surface." Brooklands does not have specific support for these broad assertions, but does cite Exergen's statements in response to requests for admissions and in prior litigation. For example, Brooklands refers to numerous statements that confirm the breadth of the '813 and '238 patents as applying to all human tissue, not only tissue in the ear, *see, e.g.*, Brooklands SOF 35, 36, 59, 62. While these statements do show that the prior patents apply not simply to tissue in the ear, using those statements to establish that the claims encompass all surface tissue of the human body cuts against Brookland's claim that the disclosure of the genus is limited.

Brooklands also cites statements about the broad applicability of the heat balance equation disclosed in the earlier patents to other parts of the body, *see, e.g.*, Brooklands SOF 41, 42, 58, and "interest" in the forehead as a location for assessing human body temperature. In addition, it cites studies showing that while numerous variables would need to be controlled for the forehead to give an accurate temperature reading, "the forehead could provide a reasonably accurate indication of internal temperature." *Id.* at 107.

Many of the "facts" referenced in Brooklands' Rule 56.1 Statement of Material Facts in support of its allegation that the '938 patent was anticipated or previously disclosed through

Dr. Pompei's prior patents come from Dr. Pompei's depositions in prior litigation. As Brooklands noted in its Response to Exergen's Rule 56.1 Statement of Material Facts, the opinions and skills of Dr. Pompei as the inventor of the '938 patent are irrelevant to a validity analysis. The question of what a person of ordinary skill would believe is determined "with reference to a *hypothetical* 'person having ordinary skill in the art,'" not with reference to the skill of an inventor. *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 454 (1985).⁶ In addition, all statements in the prior litigation occurred after Dr. Pompei had secured initial patents related to a forehead thermometer, some of which are parent patents to the '938 patent.

Dr. Pompei's statement, for example, that one reading the '238 patent "could make a, you know, a poor forehead thermometer, yes," SOF 112, is not definitive evidence that a person of ordinary skill would consider a forehead thermometer to be included in the disclosures of the '813 and '238 patents concerning a general "target" or "biological surface tissue,"

⁶ A person having ordinary skill in the art is most commonly referenced in patent eligibility analysis as the touchstone for an obviousness analysis, as discussed in *Standard Oil*, 774 F.2d at 454, and as conducted below. It is also the touchstone for part of an anticipation analysis, particularly where, as here, there is a factual question whether the disclosure of a genus discloses the particular species that is the subject of a subsequent patent.

particularly given Dr. Pompei's role as the inventor of these products and the benefit of hindsight. *Cf. Scientific Plastic Products, Inc. v. Biotage AB*, 766 F.3d 1355, 1359 (Fed. Cir. 2014) (a person of ordinary skill analysis is conducted "with the foresight of a person of ordinary skill, not with the hindsight of the inventor's successful achievement"). Exergen argues that any of the statements made in prior litigation must be understood in their contexts. Exergen admits that the '813 and '238 patents contain claims that can be used with forehead thermometers, but contends that the disclosures of the '813 and '238 patents would not have been perceived as disclosing forehead thermometry to a person of ordinary skill, at least not until after Dr. Pompei invented the forehead thermometer.

Exergen has submitted a statement of disputed material facts that it claims warrants my denying summary judgment. These concern the fact that there existed significant skepticism in the medical community regarding the possibility of accurately determining body temperature at the forehead, and that "exposed body sites, such as the forehead, were not considered appropriate sites for measurement" because of variations in temperature and because of exposure to ambient temperature. Many of the statements in Exergen's statement of facts, however, are conclusory, for example that "[t]he mere existence of the heat flow models disclosed in the '813 and '238 patents would

not have led one of ordinary skill in the art to apply the measurement techniques disclosed in those patents to the forehead."

Brooklands has presented significant, and undisputed, evidence that the '831 and '238 patents reach beyond ear tissue and claim application to human surface tissue more broadly. The undisputed facts show that these patents also disclose the heat flow models that underpin the processing step of the '938 patent. The question for me, however, is whether Brooklands has presented such clear and convincing evidence that it would be unreasonable for a fact finder to find that the '938 patent was not anticipated by the prior art at the time it was issued.

I conclude that there remain factual disputes about whether disclosure of the broad terms such as "target" or "biological surface tissue," particularly in the context of a patent that otherwise focuses primarily on the tympanic membrane, necessarily also discloses the significantly more narrow concept of measuring forehead skin. While forehead skin is certainly biological surface tissue, claiming application to the entirety of human biological surface tissue is "not a small genus," and there is a "considerable difference between" claiming biological surface tissue generally and claiming the exposed skin of the forehead, see *Atofina*, 441 F.3d at 999, such that it could be reasonable for a fact finder to conclude that the disclosures in

the prior art did not anticipate those in the '938 patent. Exergen argues that Brooklands has not presented any evidence that it would have been reasonable for a person of ordinary skill in the art to read the prior art patents to disclose measuring literally any surface tissue (would a person of ordinary skill think to measure at the nose? The sole of the feet?). While Brooklands contends that the forehead would have been a particularly obvious entry within the genus of "biological surface tissue," there is at least one significant difference between forehead skin and the other tissue discussed in the prior patents that make the forehead a less likely candidate. Whereas the specific surface tissue discussed in the earlier patents was physically protected, the forehead is an area subject to significant variations in temperature due its location and general exposure to ambient temperature.

There are outstanding questions of fact surrounding whether a person with "ordinary skill in the art" would have thought that forehead skin fell within the scope of the prior art or that the prior art would operate differently at the forehead skin relative to biological surface tissue generally due to its exposure to ambient temperature. Dr. Pompei's affidavit states that it would not have been obvious, while Dr. Lipson's affidavit states that it would have been. The Federal Circuit has made clear that where any question remains as to whether

there is a difference between a broad genus and a particular species, here that difference is at the heart of what a person of ordinary skill would have understood the disclosures of the '813 and '238 patents to be. I may not find the '938 patent invalid as a matter of law in summary judgment practice; the issue would have to be resolved through fact finding. See *OSRAM*, 701 F.3d at 706.

D. Obviousness under Section 103

A patent claim is invalid as obvious when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made by a person having ordinary skill in the art." 35 U.S.C. § 103(a). In determining obviousness, I engage in an "expansive and flexible" inquiry, considering: (1) the scope and content of the prior art; (2) the differences between the prior art and the asserted claims; (3) the level of ordinary skill in the art; and (4) any secondary considerations of obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). As with other validity-based defenses, the patent is presumed non-obvious and valid until invalidity is demonstrated by clear and convincing evidence. 35 U.S.C. § 282; see also *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009).

As discussed above, Exergen concedes that the limitations of the prior art include all aspects of the '938 claims except for that of conducting the measurements at the forehead. The factual record does not permit me to resolve as a legal matter whether the broad references to a "target" or "biological surface tissue" in the '813 and '238 patents would have made the process of measuring forehead skin and processing it to determine internal temperature obvious to a person of ordinary skill in the art.⁷

Brooklands next argues that other prior art references that involve measuring skin surface temperature or radiation at the forehead would have made this one remaining limitation obvious. The motivation to combine prior art references can arise from (1) the references themselves, (2) the knowledge of a person of ordinary skill in the art, or (3) from the type of problem to be solved. *Wyers v. Master-Lock, Co.* 616 F.3d 1231, 1238 (Fed. Cir. 2010). Brooklands contends that a person with ordinary skill in the art would consider other patents involving measurement of the forehead and would be motivated to combine

⁷ Judge Stearns' decision in *Exergen Corp. v. Kaz USA*, 2010 WL 4974167 (Aug. 20, 2015), denying a motion for summary judgment for obviousness under § 103 did not consider the same patents as those raised by the defendant in this case. However, he similarly concluded in that case that there remain factual question whether a person skilled in the art would have been motivated to combine the teachings of prior art references including '813.

them with the '813 and '238 patents. Specifically, Brooklands focuses on four patents: Kitado, Wortz, Luk, and Smith. I conclude, however, that there is insufficient support in the record to conclude that the Kitado, Wortz, Luk, and Smith patents together or individually would motivate a person with ordinary skill in the art to combine measuring the forehead with the '813 or '238 patents. I note, before addressing them specifically, that the patent examiner allowed the '938 patent over each of those patents.

The Kitado patent concerns a sleep regulation system for heating and cooling the body during sleep. While the patent does disclose measuring the forehead, the forehead is measured solely to determine surface skin temperature. In fact, the Kitado "teaches away" from using the forehead as a source for core body temperature because it describes the significant variability of measurements at the forehead at various stages of sleep. *ClearValue, Inc.*, 668 F.3d at 1344 ("alleged teaching away would be relevant to an obviousness analysis").

The Wortz patent is focused not on detecting body temperature, but on measuring involuntary responses to external stimuli. The patent similarly teaches away from using the temporal artery as a source for body temperature because the patent teaches that measurements at the forehead vary based on responses to external stimuli.

The Luk patent concerns a liquid crystal temperature adhesive sheet attached to the surface of the body, such as the forehead. The patent concerns covering part of the forehead to try to get a reading of body temperature. In contrast, the claim in '938 is directed to sensing temperature at the exposed forehead. The product claimed in the Luk patent was also subject to numerous inaccuracies, such as only providing a two degree range for a result, that could teach against using the forehead as a source of accurate measurement.

The Smith patent presents a closer question. That patent was for a thermometer that primarily takes measurements in the ear, but also specifically states, "Temperature readings can be taken at pulse points such as the wrist, under the arm, behind the knee, in the exterior ear, *on the forehead . . .*" Smith at 6:58-62 (emphasis supplied). The patent examiner initially rejected the '938 patent over the Smith patent, but ultimately allowed the claims after Exergen explained significant differences. Specifically, the Smith patent does not measure temperature or radiation, but rather electrical resistance at pulse points. It also does not explain the processing step and nowhere explains the heat flow principles on which '938 relies. These explanations would be sufficient to defeat a claim of anticipation, but they do not clearly defeat an argument of obviousness when combined with '813 and '238.

The burden, however, is not on Exergen but on Brooklands to prove obviousness by clear and convincing evidence. The Smith patent clearly claims the forehead as a feasible location for a measurement that could be converted to core body temperature. That claim combined with the concepts of measuring temperature or radiation and using heat transfer principles from the '813 and '238 patents may be sufficient to render the '938 patent obvious. However, I have not been provided with clear and convincing evidence that this is so as a matter of law. Brooklands presents Dr. Lipson's conclusory statement that he believes a person of ordinary skill in the art would combine the Kitado, Wortz, Luk and Smith patents with the '813 and '238 patents. I have not been presented with any evidence specifically about how the differences between the Smith patent's claim of measuring electrical resistance at pulse points, including the one on the forehead, and the concept of measuring temperature and radiation at the forehead skin, would be perceived by a person of ordinary skill in the art and whether such a person would think to combine these concepts. Given the lack of clear and convincing evidence on this record, I must deny the motion for invalidity on the ground of obviousness.

E. Rule 11 Sanctions

Brooklands moves for Rule 11 Sanctions against Exergen and

its counsel, Sunstein.⁸ Brooklands argues that Exergen's claims in this case are plainly frivolous and could not have been the product of a reasonable pre-litigation inquiry given admissions and statements by Exergen and Dr. Pompei in the prior Walmart and KidzMed litigations. Rule 11(b)(2) of the Federal Rules of Civil Procedure requires an attorney to certify that a reasonable inquiry was conducted to determine that "the claims, defenses, and other legal contentions are warranted by existing law or by a nonfrivolous argument for extending, modifying, or reversing existing law or for establishing new law." Where a party or lawyer advocates a frivolous claim with "culpable carelessness," that can amount to a violation of Rule 11. *CQ Int'l Co. v. Rochem Int'l, Inc.*, 659 F.3d 53, 60 (1st Cir. 2011). If a plaintiff brings suit on a claim without a good faith belief in the validity of a patent, Rule 11 sanctions may be appropriate.

The primary substance of the Rule 11 motion is that the claims at issue in the '938 patent are so clearly invalid under §§ 102 and 103 that it was frivolous to file an infringement suit because an invalid patent cannot be infringed. *Commil USA,*

⁸ Rule 11 contains significant procedural hurdles involving notice. It appears that Brooklands has surmounted those hurdles by following the proper steps in providing notice to Exergen and allowing a 21-day "safe harbor" period before filing for sanctions. Fed R. Civ. P. 11(c)(2). Exergen does not challenge the request for sanctions on procedural grounds.

LLC v. Cisco Systems, Inc., 720 F.3d 1361 (Fed. Cir. 2013).

Brooklands points to the admissions made by Exergen and Dr. Pompei as well as arguments made by Sunstein in prior litigation as evidence that the disputed claims are obviously invalid.

Exergen and Sunstein have maintained a narrow and focused legal argument related to Brooklands' claims of patent invalidity, specifically acknowledging that the prior art '813 and '238 patents disclose the "processing" step of the '938 patent but arguing that they do not disclose taking measurements at the forehead. Brooklands attacks this position as legally untenable by repeatedly contending that Exergen has made conclusory admissions that it has not made.⁹ When discussing the prior litigation, Brooklands consistently emphasizes the applicability of prior patents to forehead thermometry while omitting the fact that at least one of Exergen's existing patents at that earlier time directly claimed devices and

⁹ For example, Brooklands' repeated statements that Exergen admits that the '813 and '238 patents disclose "measuring temperature of a region of skin of the forehead/measuring radiation as target skin surface of the forehead is viewed" in the Rule 11 motion and in the §§ 102 and 103 motion clearly overstate the purported admissions by Exergen. Another example of misleading quotation by Brooklands of Exergen's "admissions" may be found on page five of Exergen's sur-reply, in which Brooklands altered a quote to reference the '813 and '238 patents in the context of a discussion of features of a forehead thermometer, when the original suit mentioned the "patents in suit" which included '813 and '238 but also included at least one patent that claimed a forehead thermometer device.

methods related to forehead thermometry. Brooklands then presents admissions about the heat balance approach in the '238 and '813 patents and that electronics disclosed in those patents may be used in a forehead thermometer as if they are admissions that the prior art patents disclose conducting measurements at the forehead. However, given the preexisting forehead-related patent, the fact that these prior art patents were included in an earlier action concerning forehead thermometers does not do as much work as Brooklands claims it does.

I find that, while Exergen made significant admissions, Exergen's prior statements do not foreclose a reasonable argument that the prior art patents do not disclose or render obvious conducting measurements at the skin of the forehead. As indicated, I do not find sufficiently clear and convincing evidence that this argument is incorrect. Brooklands' position that disclosing the "genus" of biological surface tissue necessarily discloses the "species" of forehead skin may, at the end of the day, have proven successful, but this is a complex area of law with conflicting Federal Circuit precedent, as discussed above, and would have had to await fact finding. Exergen has consistently conceded that the '813 and '238 patents have relevance to forehead thermometers, but that the full relevance was not apparent until after Dr. Pompei's invention of

the forehead thermometer. Exergen's numerous admissions that the concepts and some of the electronics ultimately were useful in creating a forehead thermometer are not admissions that forehead thermometry was disclosed or obvious in the prior art no matter how many times Brooklands states in its memoranda that they are.

As discussed above, Brooklands is correct that the '938 patent is invalid. That ruling, however, is rooted in § 101, ineligible subject matter, and not §§ 102 and 103. Brooklands does not contend that Exergen committed sanctionable conduct for maintaining the suit in light of subject matter eligibility concerns. Exergen's position that the prior art patents do not anticipate or render obvious the single step of measuring at the forehead for purposes of determining internal body temperature was not frivolous. Sanctions are not warranted.

III. CONCLUSION

For the reasons set forth more fully above, it is hereby ORDERED that:

1. The Motion for Summary Judgment of Invalidity Under 35 U.S.C. § 101 (Docket No. 46) is GRANTED;
2. The Motion for Summary Judgment of Invalidity Under 35 U.S.C. §§ 102 and 103 (Docket No. 88) is DENIED;

3. The Motion for Sanctions against Exergen (Docket No. 106)
is DENIED.

/s/ Douglas P. Woodlock
DOUGLAS P. WOODLOCK
UNITED STATES DISTRICT JUDGE